

Rejection under 35 USC 103(a)

The Examiner rejects claim 1 as obvious over Yamao et al. USP 6,030,845 (Yamao '845) in view of the English Abstract of JP 60-047962 (JP '962). Applicants traverse the rejection and respectfully request the withdrawal thereof.

The present invention is directed to a whole blood immunoassay comprising the steps of (i) mixing a whole blood sample with sensitized insoluble carrier particles to cause an immune agglutination; (ii) diluting the resulting agglutination mixture with an aqueous solution containing an erythrocyte lysing agent to lyse erythrocytes; and (iii) determining the degree of agglutination of the resulting whole blood sample.

Applicants submit that neither Yamao '845 nor JP '962 discloses an immunoassay for whole blood where the whole blood is first subjected to the agglutination reaction and then lysed subsequent to the agglutination reaction. Yamao '845 discloses an immunoassay where the agglutination reaction occurs simultaneously with hemolysis of the whole blood cells as opposed to the reaction occurring before hemolysis as in the present invention. See in particular for this description column 2, lines 25-28 of Yamao '845. Yamao '845 discloses that a lysing agent, particularly saponin, is incorporated into an insoluble particle suspension reagent onto which antibodies or

antigens specifically reacting with antigens or antibodies have been immobilized.

Likewise, JP 962 discloses a whole blood immunoassay where the lysing agent is added to the whole blood and lysis occurs prior to agglutination. Another embodiment of the JP '962 assay is that lysing and agglutination occur simultaneously. See lines 16-20 in the upper left column on page 2, where it is described that erythrocytes are lysed by a lysing agent that is added to the whole blood prior to the agglutination reaction. Alternatively, a lysing agent may be added to a suspension of carrier particles to be sensitized by antigen or antibody in a concentration of about 0.2 to 2 percent and the erythrocytes may be lysed during the agglutination reaction.

Problem solved via lysing before agglutination

The Examiner states that JP '962 teaches, "hemolyzing agents cause hemolysis of erythrocytes which interfere with the agglutination reaction." Applicants submit that although JP '962 discloses that erythrocytes are lysed by the hemolyzing agent and the ruptured cells may interfere with agglutination, [JP '962 never suggests avoiding this problem by having agglutination occur prior to hemolysis.]

Moreover, Applicants submit the primary reference Yamao '845 fails to disclose that agglutination takes place in the immunoassay prior to lysis of the whole blood. The secondary reference JP '962 fails to compensate for this deficiency in Yamao '845 as JP '962 also

fails to disclose an immunoassay where agglutination occurs prior
* to lysis of the whole blood.

In view of the deficiencies in the cited references, Applicants respectfully request that the rejection be withdrawn as no prima facie case of obviousness has been established because each and every element of the claimed invention are not disclosed or suggested by the cited art.

The Examiner also rejects claims 2-3 as obvious over Yamao '845 in view of JP '962 and further in view of Bester et al. Applicants traverse the rejection and respectfully request the withdrawal thereof.

The Examiner cites Bester for disclosing optimization of the lysing agent, such as SDS. Bester also fails to disclose having agglutination occur prior to lysis. In as much as Bester fails to compensate for the deficiencies in Yamao '845 and JP '962, Applicants submit that this rejection should also be withdrawn for the reasons stated above.

The Examiner also rejects claims 4-9 as obvious over Yamao '845 in view of JP '962 and further in view of Kosako USP 5,527,714 (Kosako '714) and Cohen et al. USP 4,851,329 (Cohen '329). Applicants traverse the rejection and respectfully request the withdrawal thereof.

The Examiner cites Kosako '714 and Cohen '329 for teaching the step of determining the concentration of particles to have an assay

with high sensitivity and specificity. In as much as Kosako '714 and Cohen '329 fail to compensate for the deficiencies in Yamao '845 and JP '962, Applicants submit that this rejection should also be withdrawn for the reasons stated above.

Lastly, the Examiner rejects claim 10 as obvious over Yamao '845 in view of JP '962 and further in view of Holmes USP 4,830,969 (Holmes '969). Applicants traverse the rejection and respectfully request the withdrawal thereof.

The Examiner relies on Holmes '969 for disclosing the reaction time and temperature. Holmes '969 however fails to disclose a whole blood immunoassay where agglutination takes place prior to hemolysis. As such, Applicants submit that Holmes '969 also fails to compensate for the deficiencies in the primary and secondary references, Yamao '845 and JP '962. Therefore, this rejection should be withdrawn.

Conclusion

As Applicants have addressed and overcome all rejections in the Office Action, Applicants respectfully request that the rejections be withdrawn and that the claims be allowed.

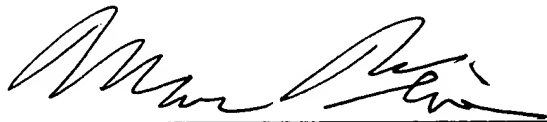
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kecia Reynolds (Reg. No. 47,021) at the telephone number of the undersigned below, to conduct an interview

in an effort to expedite prosecution in connection with the present application.

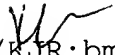
If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 

Marc S. Weiner, #32,181


MSW/KJR:bmp

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000